



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,977	09/12/2005	Alla Polozova	TRA-028.01	3230

25181 7590 08/21/2009
FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER

SHOMER, ISAAC

ART UNIT	PAPER NUMBER
----------	--------------

1612

MAIL DATE	DELIVERY MODE
-----------	---------------

08/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,977	POLOZOVA ET AL.	
	Examiner	Art Unit	
	ISAAC SHOMER	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-31,63-66,75-87,116-118 and 125-134 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3-31,63-66,75-87,116-118 and 125-134 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner thanks representative of applicant for the telephone call on July 31, informing of the amendments to the claims, and suggesting that an additional restriction requirement may be prudent due to the amendments.

The examiner further requests that in all future communications, the correct application number of 10/500,977 be placed on all submitted documents. The examiner points out that the incorrect application number of 11/634,343 has been placed on the claim set submitted 31 July 2009, however this claim set is presumed to apply to the instant application.

The examiner is unsure whether step (C)-(a) is supposed to be an alternative to the steps selected from the group consisting of (C)-(b) and (C)-(c), or whether step (C)-(a) is supposed to be done prior to the steps selected from the group consisting of (C)-(b) and (C)-(c). For the purpose of restriction, the examiner will assume that step (C)-(a) to be an alternative to the steps selected from the group consisting of (C)-(b) and (C)-(c). Hence, the examiner will restrict as if the word "or" is written after the words "containing the at least one biologically active substance encapsulated therein," as of part (C)-(a) of instant claim 1.

Election/Restrictions: Election of Species

Restriction is required under 35 U.S.C. 121 and 372.

Art Unit: 1612

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. The application is drawn to three methods of preparing liposomes containing at least one biologically active substance therein. Claim 1 reads on this species. Applicant must elect one specific method from the methods set forth below.
 - a. The method wherein liposomes (of Step A) are mixed with Medium U to form a gel (as of Step B), and subsequently mixed with Medium V to reform liposomes comprising a biologically active substance, (as of Step C-a). If applicant elects this method, then applicant has further elected the absence of Medium W.
 - b. The method wherein liposomes (of Step A) are mixed with Medium U to form a gel (as of Step B), are subsequently mixed with Medium V, and subsequently mixed with Medium W to reform liposomes comprising a biologically active substance (as of Step C-b).
 - c. The method wherein liposomes (of Step A) are mixed with Medium U to form a gel (as of Step B), are subsequently mixed with Medium V, subsequently cooled to form a waxy substance, and subsequently mixed with Medium W to reform liposomes comprising a biologically active substance (as of Step C-c).

Art Unit: 1612

2. Applicant must elect the presence or absence of the at least one biologically active substance in Medium U. Claim 1 reads on this species.
3. Applicant must elect the presence or absence of the at least one biologically active substance in Medium V. Claim 1 reads on this species.
4. Applicant must elect the presence or absence of the at least one biologically active substance in Medium W. Claim 1 reads on this species. This election is not required if Medium W is not present.
5. Applicant must elect one specific organic solvent, or one specific mixture of organic solvents. Claims 4-9 read on this species.
6. Applicant must elect one specific biologically active substance, or one specific mixture of biologically active substances. Claims 13-29 read on this species.
 - a. If applicant elects "nucleic acid" as of claim 13, applicant must further elect between plasmid DNA (as of claims 14-19), RNA (claim 27) or oligonucleotides (claims 28-29).
 - b. If applicant elects "pharmaceutically active agents," applicant must further specify a specific pharmaceutically active agent or a specific mixture of pharmaceutically active agents, as of claims 22-24.
7. Applicant must elect which fusogenic lipids are definitely present, as of claims 64-66.

Art Unit: 1612

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Upon Applicant's election of species, the result must provide a single chemical species. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

- The following claim(s) are generic:
 - Claim 1 is generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each chemical species is a distinct chemical which lacks a special technical feature in view of Citernesì (EP 0678295 A2). Citernesì, teaches a method of mixing a biologically active substance (called an "active principle" by Ugo) with a gel of lipids, followed by dilution with aqueous solution to form liposome encapsulated with active principle on column 2 lines 24-43. Citernesì further teaches on column 2 lines 35-40 that encapsulating efficiency

Art Unit: 1612

varies based upon the identity of active principle. Rowe et al. (Biophysical Journal Vol. 67, 1994, pp. 1888-1895) teaches that different solvents have different effects on lipids, as of Rowe et al. page 1888, abstract.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

Art Unit: 1612

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Joint Inventors and Rejoinder

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

Art Unit: 1612

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. S./
Examiner, Art Unit 1612

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642